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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/002,326  | 12/05/2001  | Stefan Peukert       | 02481.1759          | 3330             |
| 7590  | 01/28/2004  |                      | EXAMINER            |                  |
| Finnegan, Henderson, Farabow,<br>Garrett & Dunner, L.L.P.<br>1300 I Street, N.W.<br>Washington, DC 20005-3315 |             |                      | PATEL, SUDHAKER B   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1624                |                  |

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                               |                     |
|------------------------|-------------------------------|---------------------|
| <b>Advisory Action</b> | <b>Application No.</b>        | <b>Applicant(s)</b> |
|                        | 10/002,326                    | PEUKERT ET AL.      |
|                        | <b>Examiner</b>               | <b>Art Unit</b>     |
|                        | Sudhaker B. Patel, D.Sc.Tech. | 1624                |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) 1-3 and 5-9 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 1-3 and 5-9.

Claim(s) rejected: 10-15.

Claim(s) withdrawn from consideration: 4.

8.  The drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) ( PTO-1449) Paper No(s). \_\_\_\_\_.
10.  Other: see attached note.

## DETAILED ACTION

Applicants' communication paper dated 12/29/2003 is acknowledged.

Applicants' amendment(s) have not been entered, because they do not put the application in a condition for allowance as a single piece.

After further review and reconsideration for applicants' arguments and remarks, this application is considered not ready for allowance as a single piece for the reasons already stated in earlier Office communication papers # 8 & # 10, dated 4/23/03 & 8/22/03 respectively. Additionally, following reasons apply.

### *Election/Restrictions*

1. This application consists of a generic claim 1 with Formula I, which involves the first 6-membered ring having positions 1 to 4 occupied by variables A1, A2, A3, A4, 5<sup>th</sup> position represents a bridge –CH=CO=N- (R4)-R (3), and the 6<sup>th</sup> position is connected to a second 6-membered ring having positions 1' to 4' occupied by variables A5, A6, A7, A8, 5'th position represented by a bridge –CH-C (R30)(R31)-n (R2)-R1. Therefore, the generic formula I consists of a 6-membered ring connected to a second 6-membered ring to form 6-6' coupled bicyclic 6-6' membered rings with above stated 8 variables and 2 side chains. Thus, the instant application contains claims directed to the following patentably distinct species of the claimed invention:

- 1). Pyridine-Phenyl or
- 2). Pyridine-Pyridine;
- 3). 1,2-diazine-Phenyl or
- 4). 1,3 diazine-Phenyl or
- 5). 1,4-diazine-Phenyl or
- 6). 1,2-diazine-Pyridine or
- 7). 1,4-diazine-Pyridine or
- 8). 1,4-diazine-Pyridine or

9). Various combinations of diazine-diazine rings and other possibilities as per claims and the substituents R1-R4, R30, R31, R5 which may be further substituted by one or more substituents.

The groups as presented above, are patentably distinct inventions, each from the other because of the reasons already stated in earlier Office communication paper # 10 dated 8/22/03.

As outlined in above stated earlier Office communications, Examiner has followed the rules as per MPEP 803.02. Examiner has examined the subject matter of species of Group 1). involving Pyridine-Phenyl. Further thorough and complete examination of the application will involve additional search(es) for Groups 2). to 9). and many more groups, which will require additional time, and this, will be burden some to examiner.

The restriction/election of species was considered proper, based on scientific reasons, was maintained further, and was made FINAL in Office communication paper # 8, dated 4/23/03.

2. Various issues related to rejections made under 35 U.S.C.112 paragraphs one and second have not been resolved by the applicants. E.g. (1). claims are not limited to allowable subject matter of Group 1). as defined above. (2). Claim 1 represents a compound only, but still recites: " mixtures of any such compounds in any ratio", which may be included in a composition claim. (3). Wording of a sentence starting with: " A Pharmaceutical preparation" has not been corrected to: " A Pharmaceutical preparation" as already suggested in earlier communication(s). (4). The method of use claims 10-15 are not limited to treating of disease(s), but also to preventing of the same. Deletion of "prevention" is required. (5). Examiner maintained the rejections made under 35 U.S.C. 112 paragraph one made in Office communication paper # 8, and elaborated the same in paper # 10 dated 8/22/03, for the rejection(s) made for "prevention" of disease(s). (6). Claim(s) involving subject matter other than Group 1). Is/are not cancelled.

***Claim Objections***

3. Claims 1-3, 5-9 are objected to because of the following informalities: The claims include subject matter which is not related to invention of species of Group 1). .  
Appropriate correction is required.

***Conclusion***

***Allowable Subject Matter***

4. The following is a statement of reasons for the indication of allowable subject matter:

Claims (in part) 1-3,5-9 related to subject matter of Group 1). as elected for Phenyl-pyridine combination, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and others, set forth in Office action paper # 10 dated 8/22/03, and to include all of the limitations of the base claim and any intervening claims.

The closest prior art ref. of record Kamber et al (U.S.P. 4616002) teaches dihydro pyridine compounds, compositions and utility for treating cardiovascular disorders. See compounds of Formula (I) of abstract, and compounds of claims 1-2 in columns 55-58 wherein Ar = monocyclic aryl or a six membered monocyclic heteroaryl which are phenyl and pyridyl which are substituted by Ac, R2, R3 (in pyridine core), and aryl/pyridine core having alkyl, alkoxy, OH, COOH or, alkoxy carbonyl, carbamoyl, N-loweralkylcarbamoyl.

The instantly claimed compounds differ from Kamber by having the bridge -CO-N (R2) R1) = -CO-NH-CO-O-alkyl. The ref. '002 does teach making of compounds with bridges: -CO-NH-CH<sub>2</sub>-CO-OR<sub>7</sub> and bridge -CO-N (R4)(R3) = -CONH-Alkyl = N-loweralkylcarbamoyl.

The other art ref. Mesnard et al (Chemical Abstract DN 84:31261, also cited as Eur. J. Med. Chem. 10/3,315-22(1975)) teaches synthesis and antifibrinolytic properties of some epsilon amino acids. See compounds having CAS RN 57743-15-4. Mensnard differs from the instant compounds by not having Phenyl-pyridine combination.

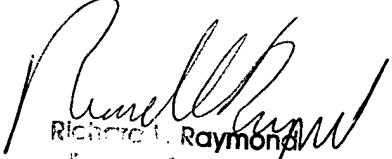
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

*The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.*

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

  
Sudhaker B. Patel, D.Sc.Tech.  
December 22, 2004.

  
Richard J. Raymond  
Supervisory Examiner  
MUKUND J. SHAH  
SUPERVISORY PATENT  
EXAMINER  
ART UNIT 1624